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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,819

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Rae Ellen Syverson

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

05/29/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

Office Action Summary	Application No. 10/803,819	Applicant(s) SYVERSON ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 13 and 15-60 is/are pending in the application.
- 4a) Of the above claim(s) 5, 12, 13 and 26-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 and 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/29/09; 2/4/09; 3/2/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of RCE, amendment and response all dated 3-2-09 is acknowledged.

Claims 1-10, 12, 13 and 15-60 are pending.

Claims 11 and 14 are canceled.

Claims 5, 12, 13 and 26-60 are withdrawn as nonelected.

Claims 1-4, 6-10 and 15-25 have been considered for examination.

In response to the arguments, the following rejection of record has been vacated:

Claims 1-4, 6-10 and 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robbins et al. (J. Clin. Microbiol. 1987) and Lambert (J Applied Microbiol.) in view of US 5,612,045 to Syverson or Syverson in view of Robbins et al and Lambert.

1. **Upon further consideration, the following new rejection is applied to the pending claims:**

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 6-10 and 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the following combinations: Lambert (J Applied Microbiol.) and US 5,612,045 to Syverson in view of US 3393678 to Pacini et al and US 4318404 to Cunningham OR unpatentable over Pacini et al in view of Cunningham, Lambert and

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Syverson OR unpatentable over Cunningham in view of Lambert, Syverson and Pacini et al.

Lambert studied the minimum inhibitory concentrations of different antimicrobial compounds against *S. aureus* and observed that phenoxyethanol and phenyl ethyl alcohol (designated as PoE and PeA respectively) are effective against *S. aureus* (abstract, page 276, col. 1, table 2, page 278, col. 2 and Discussion), even though the MICs vary with the inoculum levels. Lambert does not teach phenoxyethanol on a non-absorbent article as claimed in the instant invention.

Lambert fails to teach the claimed tampon applicator that is non-absorbent.

Syverson teaches catamenial tampons for absorbing body fluids that include an effective amount of a compound that substantially inhibit the production of exoprotein produced by Gram positive bacteria, particularly produced by *S. Aureus* (abstract, col. 3, lines 40-60). The compounds of Syverson comprise ethers, which are the same as the elected sub-species of the instant claims (col. 3, lines 61-55). Syverson teaches including effective amounts of ether compounds and combinations of other antimicrobial or antibacterial compounds (col. 5).

While Syverson teaches absorbent tampons, instant claims require tampon applicator that is non-absorbent. Syverson states that the tampon may or may not have an applicator.

Pacini et al teach catamenial devices such as tampons that have antibacterial properties as well as physical lubricity (col. 1, L 8-14). Pacini teach that polymetallic pectinates can be made into films or their dispersions may be sprayed or applied to

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materials intended for vaginal tamponing. It is suggested that the compound may be applied to the textile fabric of a tampon or to the external surface of the tubular tampon applicator (col. 2, L 38-51) because menstrual discharges provide a favorable condition for bacterial or other microbial growth (col. 3, L 1-40).

Pacini does not teach the claimed non-absorbent applicator.

Cunningham describes a tampon and its applicator, where the tampon is made of absorbent material and the applicator is made of non-absorbent material (see claim 13 of Cunningham).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the antibacterial phenoxyethanol of Lambert and the second active agent (ether compounds) taught by Syverson, both of which are effective against *S. aureus*, in the tampon applicators (Cunningham) because both Lambert and Syverson suggests employing compounds that for inhibiting toxic shock syndrome (caused by *S. aureus*) caused by the use of tampons, and Pacini suggests that antimicrobial compounds may be employed wither in the tampon fabric itself or in the enclosure that holds tampons (tampon applicator) so as to inhibit the vaginal microbial growth during menstrual cycles.

Alternatively, Pacini does not teach the claimed compounds. However, it would have been obvious for one of an ordinary skill in the art at time of the instant invention to incorporate phenoxyethanol of Lambert and the second active agent of Syverson in the tampon or applicator of Pacini because Lambert teaches phenoxyethanol is effective against *S. aureus* and Syverson also suggests the claimed second agent for the same

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reason. Further a skilled artisan would have employed a non-absorbent article for the tampon applicator because Cunningham suggests non-absorbent tampon applicators. Further, optimizing the amounts of ether (of Syverson) and phenoxyethanol of Lambert, with an expectation to provide the optimum inhibitory effect of *S. aureus* toxin production would have been within the scope of a skilled artisan.

Response to Arguments

3. Applicant's arguments filed 8-11-08 have been fully considered but they are not persuasive.

4. Firstly, the previous rejection of record has been withdrawn and the claims are now rejected over a new combination of references. The examiner will not address applicants' arguments regarding the teachings of Robbins because the teachings of Robbins are no longer applicable.

Applicants argue that Lambert discloses a method of examining the effect of inoculum size on the degree of inhibition observed with respect to inhibitor concentration. Specifically, the inoculum size dependencies of phenethyl alcohol, phenoxyethanol, p-chloro-m- cresol, trichloro-phenol, thymol, and dodecyltrimethylammonium bromide against *S. aureus* were analyzed. It is argued that for all inhibitors examined, it was found that at lower inoculum levels, there was a greater biocidal effect, whereas at higher inoculum levels, there was a greater degree of quenching of the biocide, causing the inhibitor to act more as a simple (sublethal)

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inhibitor. Applicants agree that the method developed in Lambert may be used to quantify the effect in the region between reversible and irreversible damage, or sublethal injury to cell death and that according to Lambert that phenethyl alcohol is a better inhibitor than phenoxyethanol against S. aureus.

Applicants' arguments are not persuasive because the teachings of Lambert are analogous to those of Syverson. Further, known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art. In this regard, Lambert teaches different compounds and their effect on the reversible and irreversible damage to various inoculum levels of S. aureus. Hence the argument that Lambert fail to disclose the use of phenoxyethanol (or any compound having the structure of the first active ingredient) in combination with a second active ingredient is not persuasive.

With respect to Lambert, applicants' argue that phenethyl alcohol is a better inhibitor than phenoxyethanol against S. aureus, the arguments are not persuasive because the teaching of Lambert that phenethyl alcohol is superior to phenoxyethanol does not lead to the conclusion that the latter is not effective in inhibiting S. aureus.

Applicants argue that the references fail to teach the non-absorbent substrate being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche for insertion into the vagina for inhibiting exoproteins from Gram positive bacteria as required in claim 1. It is argued that Syverson teaches absorbent articles and not non-absorbent articles.

Applicants' arguments are not persuasive because newly cited references (Pacini et al (US 3393678) and Cunningham (US 4318404) has been cited to show that antimicrobial agents are known to be applied in the tampon or its applicator, which may be non-absorbent and hence the argument regarding the lack of non-absorbent article of Syverson is moot. Thus, the argument made by applicants that a combination of first and second active agents being present on a non-absorbent substrate are not taught is not persuasive because it would have been obvious for one of an ordinary skill in the art at the time of the instant invention that exoprotein inhibiting compounds may be applied on nonabsorbent tampon articles and still achieve the desired inhibitory activity. One of an ordinary skill in the art would have been motivated to include phenoxyethanol of Lambert & the second compound of Syverson on non-absorbent tampon applicators of Cunningham with a reasonable expectation that phenoxyethanol and the second active agent of Syverson provide effective inhibition of exoprotein produced by *S. aureus*.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
May 13, 2009